

Gyrus Medical Inc. Open Forceps
ACMI Corporation
136 Turnpike Road
Southborough, MA 01772

Special 510(k) Notification
Summary of Safety and
Effectiveness
August 4, 2006

510(k) Summary of Safety and Effectiveness
ACMI Corporation
Gyrus Medical Inc. Open Forceps

AUG 10 2006

K061975

General Information

Manufacturer: Gyrus Medical Inc.
6655 Wedgwood Rd.
Maple Grove, MN 55311-3602

Establishment Registration Number: 2183680

510(k) Submitter: ACMI Corporation
136 Turnpike Rd.
Southborough, MA 01772-2104

Establishment Registration Number: 3003790304

Contact Person: Terrence E. Sullivan
Director, Regulatory Affairs

Date Prepared: August 4, 2006

Device Description

Classification Name: Electrosurgical cutting and coagulation device and accessories
(21 CFR 878.4400), Class II
General and Plastic Surgery Panel

Trade Name: Gyrus Medical Open Forceps

Generic/Common Name: Electrosurgical Instruments

Predicate Device

Gyrus Medical Open Forceps K024286

Intended Uses

The Gyrus Medical Inc. Open Forceps are intended for electrosurgical coagulation, mechanical grasping and dissection of tissue, and sealing of vessels up to 7mm, during the performance of open general surgical procedures.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2006

ACMI Corporation
% Mr. Terrence E. Sullivan
Director, Regulatory Affairs
136 Turnpike Road
Southborough, Massachusetts 01772-2104

Re: K061975

Trade/Device Name: Gyrus Medical Inc. Open Forceps
Regulatory Number: 21 CFR 878.4400
Regulatory Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 28, 2006
Received: August 1, 2006

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

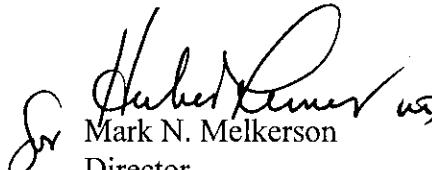
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Terrence E. Sullivan

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson

Director

Division of General, Restorative

and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Gyrus Medical Inc. Open Forceps
ACMI Corporation
136 Turnpike Road
Southborough, MA 01772

Special 510(k) Notification
Statement of Intended Use
August 4, 2006

Device Name: Gyrus Medical Inc. Open Forceps

510(k) Number: K061975

Indications for use:

The Gyrus Medical Inc. Open Forceps are intended for electrosurgical coagulation, mechanical grasping and dissection of tissue, and sealing of vessels up to 7mm, during the performance of open general surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-the-Counter Use: _____

(Per 21 CFR 801.109)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K061975